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To Pharmacy Compliance Team
From Karl Zillgitt
Date 7/31/18
Subject Pharmacy Compliance Team Meeting 2nd Quarter 2018

Introduction

On Tuesday, July 31st, 2018, at 3:30 p.m., I met with Jillanne Smith, Toan Do, David Kirkus, Jennifer Warren, Michael Hernandez, Bill Howard, Candin Ruvolo, Toni Hiers, Dain Rusk and Adam Maingot for the 2nd quarter, 2018 Pharmacy Compliance Team meeting. The purpose of the meeting was to determine the status of Publix's compliance with applicable laws and regulations. A copy of the Metrics for the 2nd quarter are attached.

Discussion

The first order of discussion was Publix's compliance under the Pharmacy Metrics. Under the first risk, the Team reported 0 known Customer Complaints, Board of Pharmacy inquiries or physician complaints of a misfill where no corresponding QRE was on file. For the second metric, the percentage of prescriptions with a QRE was .009%, the same as last quarter and the trend continues to point downward.

There were no governmental agency violations for filing a false claim. There were 3 episodes of a pharmacy associate embezzling prescription drugs. The incident discussed by the Team involved a Pharmacy tech who rang a prescription through under another customers name, and failed to provide the receipt to that customer so that the customer would not know he was issued 5 prescriptions instead of 4. Pharmacy discovered the error because the customer who should have received the Oxycodone complained and was reissued the prescription. The incident was reported to DEA on Form 106, and the insurance claim was not reversed because the patient did receive their medication. There were HIPAA concerns because the patients information was on the bottle that was stolen. Bill agreed to talk with Heather Dudman to obtain any cases where a Pharmacy interview reveals employee embezzlement of prescription drugs.

There were 3 Government agency investigations regarding a Publix pharmacy or Pharmacy personnel and controlled substances. Two did not appear to be focused on the Pharmacy, but on the patients receiving the medications. The FBI was investigating South Florida pharmacies that issued drugs to patients involved

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in a widespread sting operation. It does not appear that the pharmacists were in cahoots with the perpetrators (doctors/patients). However, there were scripts with missing information, such as the physician's DEA # and there is also evidence that Publix did not fill some prescriptions because of red flags. The FBI agent has stated that he doesn't believe Publix was complicit, but the community pharmacies may have been complicit.

For the metric "# of suspicious orders reported to DEA through the SOM system", there were none. However, the Team discussed the Suspicious order monitoring system and believes it does not work. All of the algorithms (red flags) that can be triggered on the system have been shut down except for 2 relating to the size of the order, so that only a couple of orders were stopped last year. Vendor does not want to work with Publix in making their program work on Publix's system. Also, even if an order were stopped by the Suspicious ordering system, the store could simply purchase the drugs from the wholesaler. Thus, the Team believed that this metric should be removed.

There were no pharmacies with a complaint filed against them by a State agency where probable cause was found. The Team discussed what this metric should produce, and it was determined that Publix should be reporting any notices of violation from a State or Federal agency.

7 out of 198 Pharmacy techs or 3.54% had not registered with the state within 180 days of entering the JC, within goal. All of the pharmacy techs that had not registered were removed from the pharmacy. 3 out of 679 Pharmacy associates or .44% had not completed annual renewal fraud and abuse renewal training, within goal. Jillanne advised that Fraud, Waste & Abuse data in Learning was not accurate, as there were a lot more Pharmacy associates being trained than what was being reported by the system. There were 4 out of 395 associates that had not completed Fraud, Waste and Abuse training within 45 days of hire, or 1.01%, within goal. There were 13 out of 395 associates that had not completed Methguard CBT within one week of hire, or 1.01%, within goal.

In a random sampling taken in the 1st quarter of Medicaid prescriptions, 0 out of 100 prescriptions sampled were not written on tamper resistant prescription pad.

Finally, Dain advised that he had not confidence that we were measuring the right metrics where we had the greatest risk. Thus, I advised that we should conduct another risk assessment, and emailed Candin Ruvolo to see if we can commence a Risk Assessment under the new program. Thus, the Q3 meeting will be rescheduled with more time to complete the Risk Assessment.